UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICALS U.S.A., INC., Plaintiff, vs. PAR PHARMACEUTICAL COMPANIES, INC., and PAR PHARMACEUTICAL, INC., Defendants.	C.A. No. 13-cv-1524-SLR
TAKEDA PHARMACEUTICALS U.S.A., INC., Plaintiff, v. AMNEAL PHARMACEUTICALS, LLC, Defendant.	C.A. No. 13-cv-1729-SLR
TAKEDA PHARMACEUTICALS U.S.A., INC., Plaintiff, v. WATSON LABORATORIES, INC., Defendant.	C. A. No. 14-cv-268-SLR

PLAINTIFF TAKEDA PHARMACEUTICAL U.S.A., INC.'S REPLY IN SUPPORT OF ITS MOTIONS FOR LEAVE TO FILE AN AMENDED COMPLAINT

TABLE OF CONTENTS

I. INTRODUCTION 1

II. ARGUMENT 2

A. The Court Has Subject Matter Jurisdiction Over Takeda's Claims for Declaratory Judgment of Contributory Infringement 2

1. Par 3

2. Watson 6

B. Takeda's Contributory Infringement Claims Are Not Futile 10

1. Takeda's Contributory Infringement Claims Are Not Contrary To The Hatch-Waxman Framework. 10

2. Takeda Has Alleged The Requisite Elements of Contributory Infringement 11

C. Takeda Brings This Motion in Good Faith Without Undue Delay and There Would Be No Undue Prejudice to Par if the Court Grants Takeda's Motion 14

III. CONCLUSION 15

TABLE OF AUTHORITIES

Cases

Abbott Diabetes Care, Inc. v. DexCom, Inc.,
No. 05-590, 2006 WL 2375035 (D. Del. Aug. 16, 2006) 3

Abbott Labs v. Zenith Labs., Inc.,
934 F. Supp. 925 (N.D. Ill. 1995) 4

Abbott Labs. v. Baxter Healthcare Corp.,
No. 04 C 836, 2004 WL 1878291 (N.D. Ill. Aug. 16, 2004) 5

Abraxis Bioscience, Inc. v. Navinta, LLC,
640 F. Supp. 2d 553 (D.N.J. 2009), *rev'd and vacated on other grounds*, 625 F.3d 1359 (Fed. Cir. 2010) 12

Adams v. Gould, Inc.,
739 F.2d 858 (3d Cir. 1984) 15

Allergan Inc. v. Alcon Labs., Inc,
324 F.3d 1322 (Fed. Cir. 2003) 7, 8

Amgen, Inc. v. F. Hoffman-LaRoche Ltd.,
456 F. Supp. 2d 267 (D. Mass. 2006) 5

AstraZeneca Pharm. LP v. Apotex Corp.,
669 F.3d 1370 (Fed. Cir. 2012) 10, 11

Aventis Pharma Deutschland GmbH v. Cobalt Pharms., Inc.,
355 F. Supp. 2d 586 (D. Mass. 2005) 14

Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S,
132 S. Ct. 1670 (2012) 10

Cephalon, Inc. v. Sandoz, Inc.,
No. 11-821, 2012 WL 682045 (D. Del. Mar. 1, 2012) ..... passim

Cephalon, Inc. v. Watson Pharm., Inc.,
629 F. Supp. 2d. 338 (D. Del. 2009) 5, 6

ClearValue, Inc. v. Pearl River Polymers, Inc.,
735 F. Supp. 2d 560 (E.D. Tex. 2010) *rev'd on other grounds*, 668 F.3d 1340 (Fed. Cir. 2012) 12

Dawson Chem. Co. v. Rohm & Hass Co.,
448 U.S. 176 (1980) 13

Dole v. Arco Chem. Co.,
921 F.2d 484 (3d Cir. 1990) 1

Eisai Co., Ltd. v. Mutual Pharm. Co.,
No. 06-3613, 2007 WL 4556958 (D.N.J. Dec. 20, 2007) 8, 9

Eon Labs, Inc. v. Pfizer Inc.,
No. 05-0002, 2005 WL 1705295 (S.D.N.Y. July 19, 2005) 5

Glaxo, Inc. v. Novopharm, Inc.,
110 F.3d 1562 (Fed. Cir. 1997) 2, 4, 5, 7

Hewlett-Packard Co. v. Bausch & Lomb Inc.,
909 F.2d 1464 (Fed. Cir. 1990) 7

In re Rosuvastatin Calcium Patent Litigation,
MDL No. 08–1949, 2008 WL 5046424 (D. Del. Nov. 24, 2008) 9

Intermedics, Inc. v. Ventritex, Co.,
991 F.2d 808, 1993 WL 87405, at *4 (Fed. Cir. 1993) 4, 8

Kos Pharm., Inc. v. Barr Labs., Inc.,
242 F. Supp. 2d 311 (S.D.N.Y. 2003) 5

Lang v. Pac. Marine & Supply Co.,
895 F.2d 761 (Fed. Cir. 1990) 5

Lucent Techs., Inc. v. Gateway, Inc.,
580 F.3d 1301 (Fed. Cir. 2009) 12

MedImmune, Inc. v. Genentech, Inc.,
549 U.S. 118 (2007) 2

Novartis Pharms. Corp. v. Wockhardt USA LLC,
No. 13-1028, 2013 WL 5770539 (D.N.J. Oct. 23, 2013) 11, 13

Reckitt Benckiser Pharms., Inc. v. Biodelivery Sciences Int'l, Inc.,
No. 13-760, 2014 WL 2119822 (E.D.N.C. May 21, 2014) 9

Sigma-Tau Pharms., Inc. v. Schwetz,
288 F.3d 141 (4th Cir. 2002) 11

Site Microsurgical Sys., Inc. v. Cooper Cos.,
797 F. Supp. 333, 336 (D. Del. 1992) 10

Sony Corp. of Am. v. Universal City Studios, Inc.,
464 U.S. 417 (1984) 13

Telectronics Pacing Sys., Inc. v. Ventritex Co.,
982 F.2d. 1520 (Fed. Cir. 1992) 3

Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.,
482 F.3d 1330 (Fed. Cir. 2007) 6

Toshiba Corp. v. Imation Corp.,
681 F.3d 1358 (Fed. Cir. 2010) 13

Warner-Lambert Co. v. Apotex Corp.,
316 F.3d 1348 (Fed. Cir. 2003) 7

Statutes

21 U.S.C. § 355(j)(2)(A) 4

21 U.S.C. § 360d 3

21 U.S.C. § 360e 3

35 U.S.C. § 271(e)(2)(A) 4

Rules

FED. R. CIV. P. 15(a)(2) 1

Federal Circuit Rule 32.1 8

I. INTRODUCTION[1]

Par [2] and Watson (collectively, "Defendants") here seek a result that this Court has previously recognized as unfair in Hatch-Waxman litigation, namely, permission to sell their "generic as soon as [their] ANDA[s are] approved by the FDA without responsibly resolving all the patent issues related to" their products. *Cephalon, Inc. v. Sandoz, Inc.* ("*Cephalon II*"), No. 11-821, 2012 WL 682045, at *6 (D. Del. Mar. 1, 2012).

There is no dispute as to the commercial realities of the colchicine market. Takeda's amended complaint alleges that less than one quarter of one percent of colchicine prescriptions in the U.S. in recent years are written for the treatment of FMF. (*See* D.I. 55 in No. 13-cv-1524, Exs. G-J.) In other words, colchicine is, as it always has been, a product used overwhelmingly to treat gout. Neither Watson nor Par disputes this fact. Indeed, Watson emphasized before this Court and in its opposition brief its belief that it is critical to supply generic colchicine to the "over eight million" people who suffer from gout in the United States. (*See* D.I. 71-1 in No. 13-1524 ("Yang Decl."), Ex. B at 17:1-24; 19:2-13; D.I. 29 in No. 14-cv-268 [Watson Br.] at 5.) In short, Defendants intend to place into the stream of commerce a colchicine product that has no substantial use other than to treat gout in violation of Takeda's patents. That is the essence of contributory infringement.

Leave to amend should be "freely given when justice so requires." FED. R. CIV. P. 15(a)(2); *Dole v. Arco Chem. Co.*, 921 F.2d 484, 486-87 (3d Cir. 1990). The primary ground on which Defendants oppose Takeda's motion is futility, and specifically, their contention that the Court

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[1] Concurrently herewith, Takeda has filed under seal in the Par docket a short one-page supplement in support of its motion as to Par that references Par confidential information.
[2] "Par" refers to Par and Amneal. (*See* D.I. 44 in No. 13-cv-1729 [Notice of Joinder].)

does not have jurisdiction to adjudicate Takeda's declaratory relief claim. However, each Defendant has engaged in substantial activities (e.g., preparation of their ANDAs, Paragraph IV patent challenges, and pursuit of FDA approval) to enter the market with a gout medication that give rise to an immediate and real controversy as to anticipated infringement that satisfies the declaratory judgment standard set out in *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007). Each Defendant has engaged in "meaningful preparation" towards infringing activity, and has further indicated an intent to persevere in that course of conduct. *See Glaxo, Inc. v. Novopharm, Inc.*, 110 F.3d 1562, 1571 (Fed. Cir. 1997). Takeda's declaratory relief claim alleges all of the elements of contributory infringement and the viability of that claim is not affected by the cases that Defendants cite involving claims for direct infringement or inducement. Nor have Defendants identified any bad faith or undue delay by Takeda, or prejudice to themselves, that would justify denial of the motion. Takeda respectfully asks the Court to grant its motions.

II. ARGUMENT

A. The Court Has Subject Matter Jurisdiction Over Takeda's Claims for Declaratory Judgment of Contributory Infringement

Defendants argue that the Court lacks subject matter jurisdiction over Takeda's declaratory relief claims relating to the gout patents. Takeda, however, readily meets the *MedImmune* standard. *See MedImunne,* 549 U.S. at 127.

Moreover, Takeda has properly asserted claims for infringement of its FMF patents. Since there is already a justiciable controversy directed to Defendants' post-approval activities, the appropriate and efficient result is to adjudicate all patent disputes directed to the Defendants' proposed ANDA products, including Takeda's claims for contributory infringement. Not doing so would have the same consequences this Court identified in *Cephalon II*, potentially allowing

Defendants to "market [their] generic as soon as [their] ANDA is approved by the FDA without responsibly resolving all the patent issues related to said product[s]." 2012 WL 682045, at *6.

1. Par

Par argues that the possibility of its selling generic Colcrys® to physicians or patients to treat gout according to Takeda's patented methods is too speculative to support declaratory relief jurisdiction. However, as discussed below, this Court has previously recognized a generic pharmaceutical company's efforts to obtain FDA approval to sell a drug subject to patent protection gives rise to a justiciable controversy under the Declaratory Judgment Act ("DJA").

The primary case upon which Par relies, *Abbott Diabetes Care, Inc. v. DexCom, Inc. ("DexCom")*, No. 05-590, 2006 WL 2375035, at *3 n.3 (D. Del. Aug. 16, 2006), involved medical devices, not drug products. This is a critical difference, as drug products are subject to a statutory scheme (Hatch-Waxman) designed to allow patent litigation to proceed when an ANDA is filed; there is no such equivalent for medical devices. The FDA's approval process for medical devices requires extensive pre-approval *clinical testing* to demonstrate compliance with applicable performance standards. *See, e.g.*, 21 U.S.C. §§ 360d & 360e. The patentees asserting infringement claims in *DexCom* (as well as in the two other medical device decisions cited by Watson) either sought to challenge the very use and sale activity required by the FDA for approval of medical devices, or brought speculative claims based on initial designs that were subject to modification through the clinical trial process. *See Telectronics Pacing Sys., Inc. v. Ventritex Co.*, 982 F.2d. 1520, 1527 (Fed. Cir. 1992), and *Intermedics, Inc. v. Ventritex, Co.*, 991 F.2d 808, 1993 WL

87405, at *4 (Fed. Cir. 1993).[3] A generic company that submits an ANDA does not perform clinical testing to establish safety and efficacy. *See* 21 U.S.C. § 355(j)(2)(A)(ii)-(iv) (requiring certifications that the active ingredient, route of administration, dosage form, and strength of the proposed generic are the same as the reference drug, and of bioequivalence). A declaratory relief claim directed to such a submission therefore typically focuses on *post-approval* activities, and does not threaten to prevent use or sale activity specifically authorized by Congress. Not surprisingly, therefore, courts considering the justiciability of declaratory relief claims directed to ANDAs often have reached different results than those in the medical device cases.

In the leading case, *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997), the patentee brought claims against an ANDA filer for infringement of one patent under section 271(e)(2)(A) of the Hatch-Waxman Act and also asserted a declaratory relief claim under a second patent directed to a method of manufacture. Because section 271(e)(2)(A) does not apply to method of manufacture claims, the patentee's only avenue for adjudicating this claim was the DJA. In *Glaxo*, the Federal Circuit rejected the argument, also advanced by Defendants here, that allowing a declaratory relief claim was somehow inconsistent with Congressional intent in enacting the safe harbor provisions of the Hatch-Waxman Act.

> The protected status of Novopharm's activities leading to its submissions to the FDA does not by itself prevent the district court from considering Glaxo's request for declaratory relief *because such relief is directed to the time after the ANDA is approved, when § 271(e)(1) no longer [applies]*.

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[3] In *Abbott Labs v. Zenith Laboratories, Inc.*, 934 F. Supp. 925, 933, 939 (N.D. Ill. 1995), also cited by Par, the patentee failed to list its patent in the Orange Book in conjunction with its NDA. This case is factually different, and that court's refusal to extend jurisdiction under the DJA is inconsistent with the Federal Circuit's later decision in *Glaxo*.

Id. at 1571 (emphasis added). The Court noted that declaratory relief claims directed to post-approval activities fell within the principle that a "patentee may seek a declaration that a person will infringe a patent in the future," *id.* at 1570, and articulated the following test for the justiciability of a claim based upon future infringement:

> the patentee must demonstrate that two elements are present (1) the defendant must be engaged in an activity directed toward . . . an infringement charge . . . or be making meaningful preparation for such activity; and (2) acts of the defendant must indicate a refusal to change the course of its actions in the face of acts by the patentee sufficient to create a reasonable apprehension that a suit will be forthcoming.

Id. at 1571 (quoting *Lang v. Pac. Marine & Supply Co.*, 895 F.2d 761, 764 (Fed. Cir. 1990)). Applying this standard, the Federal Circuit held that Novopharm's submission of an ANDA supported declaratory relief jurisdiction, even though Novopharm had not yet obtained FDA approval and would not be able to sell its product for at least 17 months after the filing of suit. *Id*. at 1564, 1571. Numerous decisions after *Glaxo* have followed its jurisdictional ruling. *See Cephalon II*, 2012 WL 682045, at *5; *Amgen, Inc. v. F. Hoffman-LaRoche Ltd*., 456 F. Supp. 2d 267, 278 (D. Mass. 2006); *Eon Labs, Inc. v. Pfizer Inc.*, No. 05-0002, 2005 WL 1705295, at *3 (S.D.N.Y. July 19, 2005); *Abbott Labs. v. Baxter Healthcare Corp*., No. 04 C 836, 2004 WL 1878291, at *6 (N.D. Ill. Aug. 16, 2004); *Kos Pharm., Inc. v. Barr Labs., Inc.*, 242 F. Supp. 2d 311, 317-18 (S.D.N.Y. 2003).

In a subsequent decision involving Watson, not cited by defendants, this Court exercised declaratory relief jurisdiction over an induced infringement claim based on Watson's filing of an ANDA, holding that the DJA provided an independent basis for jurisdiction. *Cephalon, Inc. v. Watson Pharm., Inc*., 629 F. Supp. 2d. 338, 350-51 (D. Del. 2009) (Robinson, J.) ("*Cephalon I*") ("[W]hile claims under 35 U.S.C. § 271(e)(2) are, 'by [their] very nature, speculative to a certain degree, . . . [they are] not sufficiently so [as] to contravene the case or controversy requirement . . .

of Article III,' . . . or, by logical extension, *the case or controversy requirement of the Declaratory Judgment Act*." (emphasis added) (quotation omitted)). This Court held that the defendants' filing of an ANDA and "intent to manufacture, market and sell potentially infringing products in the event that the FDA approves the ANDA" gave rise to a "real and immediate" controversy sufficient to support a declaratory relief claim. *Id*. at 351. More recently, in *Cephalon II*, this Court held that jurisdiction would lie over Cephalon's claims for possible post-approval patent infringement under "35 U.S.C. § 271(e)(2) and/or 28 U.S.C. § 1338(a)," again indicating an independent basis for jurisdiction. 2012 WL 682045, at *6. This Court further noted that refusing to adjudicate the claim would have given Sandoz "an advantage not contemplated under the careful balancing act of the statutory scheme, to wit, the ability to market its generic as soon as its ANDA is approved by the FDA without responsibly resolving all the patent issues related to said product." *Id*. at *6. *Cf. Teva Pharm. USA, Inc. v. Novartis Pharm. Corp*., 482 F.3d 1330, 1342 (Fed. Cir. 2007) (criticizing *patentee's* efforts to exclude certain of its Orange Book listed patents from Hatch-Waxman litigation as inconsistent with the goal of the Hatch-Waxman Act to "obtain patent certainty"). Defendants here seek precisely this same unfair advantage.

In short, a claim of declaratory relief directed to an ANDA filer's future post-approval infringement satisfies the "case or controversy" requirement for jurisdiction under the DJA.

2. Watson

Watson spends several pages in its brief arguing that Takeda's claims under its gout patents do not lie under section 271(e) of the Hatch-Waxman Act. (*See* Watson Br. at 10-13.) However,

Takeda does not allege that they do. Instead, as discussed in Takeda's opening brief and above, Takeda's claims arise under section 271(c) and the DJA.[4]

With regard to the DJA, Watson's argument that jurisdiction is lacking rests on a facially erroneous premise. Watson argues that, "like any other case outside of the Hatch-Waxman framework, [patent infringement claims] can be determined only upon actual infringement." (Watson Br. at 13.) Watson thus completely ignores the Federal Circuit's opinion in *Glaxo* that a "patentee may seek a declaration that a person will infringe a patent in the future." 110 F.3d at 1570. As noted in section II.A.1, such claims are justiciable where the plaintiff alleges, as Takeda has done here, that the defendant has made "meaningful preparation" towards infringing activity, and has indicated intent to persevere in its potentially infringing course of conduct.

Watson further misstates the law in arguing that section 271(e) is the only basis for jurisdiction over a claim based on an ANDA. (*See* Watson Br. at 11 ("Section 271(e) provided a basis for subject matter jurisdiction in certain cases that otherwise would have failed to meet the standard for lack of case or controversy") (citing *Allergan Inc. v. Alcon Labs., Inc*, 324 F.3d 1322, 1332 (Fed. Cir. 2003)).) In fact, *Allergan* reached precisely the opposite conclusion. In holding that an induced infringement claim based on post-FDA-approval activities satisfied the Constitutional "case or controversy" requirement, the Federal Circuit relied in part on non-Hatch-

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[4] In *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003), cited by Watson, the Federal Circuit held that the plaintiff could not establish *inducement* liability where the ANDA did not seek approval for, or encourage use of the generic drug to treat, the patented indication. *Id.* at 1364-65. The Court noted that an inducement claim required "specific intent and action to induce infringement," and thus could not be established without "evidence that Apotex has or will promote or encourage doctors to infringe . . . ." *Id.* at 1364. This holding is not relevant to Takeda's contributory infringement claim, which does not require specific intent. "[O]nly proof of a defendant's *knowledge*, not *intent*, that his activity cause infringement [i]s necessary to establish contributory infringement." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469 (Fed. Cir. 1990).

Waxman declaratory judgment law. *Id*. at 1332 ("[I]n the setting of a *declaratory judgment action*, we have held that Article III does not preclude an action by a potential defendant for a determination that its conduct does not induce infringement, *prior to any acts of infringement having taken place*." (emphases added)). In addition, as noted above, the Federal Circuit in *Glaxo* held that declaratory relief jurisdiction existed to determine the legality of the ANDA filers' post-approval conduct.

Watson fails to cite either this Court's prior decisions, or the *Glaxo* court's governing declaratory relief analysis. Instead, Watson improperly relies on an unpublished decision, *Intermedics*,[5] and a district court decision with which this Court has expressed sharp disagreement, *Eisai Co., Ltd. v. Mutual Pharm. Co.*, No. 06-3613, 2007 WL 4556958 (D.N.J. Dec. 20, 2007).

Aside from its not having precedential force, as noted above, *Intermedics* involved a challenge to activities of a medical device manufacturer in developing clinical testing data and making sales required for FDA approval; activities specifically exempted from liability by 271(e)(1). *Intermedics*, 991 F.2d 808, at *4. In affirming the district court's refusal to exercise declaratory jurisdiction, the Court emphasized that "[t]o permit Ventritex to be protected from direct suit for infringement [under section 271(e)(2)] and yet allow the same activities to be subject to suit in a declaratory judgment action would be nonsensical." *Id.* Importantly, the current case is not directed to the Defendants' protected efforts to seek FDA approval, but rather to their post-approval conduct.

Eisai was a unique case where the patentee failed to provide notice to the FDA and generic companies of the patents relating to its branded product. *Eisai*, 2007 WL 4556958, at *4, *14. As a

[5] Under Federal Circuit Rule 32.1, unpublished Federal Circuit opinions issued prior to 2007 may not be cited as precedent.

result, the generic company did not file the Paragraph IV certification that typically triggers a Hatch-Waxman suit. *See id.* at *4.[6] In *Cephalon II*, this Court also faced a factually analogous situation to the *Eisai* case. This Court expressed its "disagree[ment] with the [*Eisai* court's] sweeping conclusion that the absence of a Paragraph IV certification limits, as a matter of law, the court's subject matter jurisdiction under both 35 U.S.C. § 271(e)(2) and 28 U.S.C. § 2201 [the DJA]," 2012 WL 682045, at *5, and considered the patentee's negligence in failing to provide notice of its patents "so egregious" that the patentee "forfeited" its ability to seek either § 271(e)(2) or declaratory relief, *Id.* at *4. Noting that the patentee in the case before it, unlike the patentee in *Eisai*, properly had brought suit under *other* patents that it had listed in a timely fashion (and which had prompted paragraph IV certifications from the defendant), this Court exercised its discretion to adjudicate the remaining claims as well. *Id.* at *5. The same result should apply here.[7]

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[6] Even the *Eisai* Court recognized the unusual factual circumstances which prompted its holding. *See* 2007 WL 4556958 at *14 ("Due to the unusual developments which led to the instant dispute, the Court is confident that this situation does not and will not occur with any great frequency.").

[7] The other cases cited by Watson do not suggest a different result. In *Reckitt Benckiser Pharmaceuticals, Inc. v. Biodelivery Sciences International, Inc.*, No. 13-760, 2014 WL 2119822 (E.D.N.C. May 21, 2014), the court simply followed *Eisai* and *DexCom* without extended analysis or any reference to *Glaxo* or the decisions of this Court cited above. 2014 WL 2119822, at *3-4. In *In re Rosuvastatin Calcium Patent Litigation*, MDL No. 08–1949, 2008 WL 5046424 (D. Del. Nov. 24, 2008), Magistrate Judge Stark recommended dismissal of a declaratory relief claim that was based "on the same patent and . . . on all the same facts" as a section 271(e)(2) Hatch-Waxman claim on the basis that the claim would either be wholly redundant of the 271(e)(2) claim – and thus unnecessary – or would target activity specifically exempted from liability by section 271(e)(1), such as preparation of an ANDA. *Id*. at *12-13. As noted above, this Court reached different conclusion on jurisdiction in *Cephalon I* and *II*. In any event, unlike the claim in *Rosuvastatin*, Takeda's declaratory judgment claim for contributory infringement is non-duplicative and essential to fully resolve the parties' dispute.

B. Takeda's Contributory Infringement Claims Are Not Futile

1. Takeda's Contributory Infringement Claims Are Not Contrary To The Hatch-Waxman Framework.

For an amendment to be denied for futility, the "claim must be futile as a matter of law rather than merely unlikely as a matter of fact." (*See* D.I. 70 in No. 13-cv-1524 [Par Br.] at 6 (citing *Site Microsurgical Sys., Inc. v. Cooper Companies, Inc.*, 797 F. Supp. 333, 336 (D. Del. 1992)).) Here, no legal impediment precludes Takeda's contributory infringement claims.

Watson provides an extensive discussion of the section viii "carve-out" procedure whereby a generic company can forego FDA approval for uses of a medication covered by the innovator's patent. As noted in a passage quoted in Par's brief, however, the section viii carve-out was intended to expedite approval of drugs that the FDA has approved for *unpatented* uses: "[t]he Hatch-Waxman Amendments authorize the FDA to approve the marketing of a generic drug for particular *unpatented* uses; and section viii provides the mechanism for a generic company to identify those uses, so that a product with a label matching them can quickly come to market." (Par Br. 8-9 (quoting *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1681 (2012) (emphasis added)).) Here, Defendants are *not* using the carve-out as envisioned by Congress, as their respective products have no substantial use other than those covered by Takeda's patents.

Watson's citation to *AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370 (Fed. Cir. 2012), is equally unavailing. *AstraZeneca* merely holds that a section 271(e) claim does not lie against a generic company that seeks FDA approval only for *unpatented* (and presumably substantial) uses of a drug. *See id.* at 1379. The Court had no occasion to, and did not, consider the situation presented here, i.e., where the only substantial use of Watson's product is covered by other innovator patents. Tellingly, however, the Court did indicate that conduct of the type engaged in here by the defendants should not be without remedy, noting that an "unfounded Section viii statement [would not] necessarily immunize an ANDA that actually seeks approval for

a patented treatment or necessarily leave the patentee without recourse under § 271(e)(2)." *Id.* at 1380. Takeda here alleges that Defendants are using their section viii statement to allow them to sell their products almost exclusively to gout patients, in violation of Takeda's gout patents.[8]

Nothing in the legislative history or case law suggests that Congress intended to allow generic companies to misuse the section viii carve-out procedure to place a product on the market that would be (i) "approved" only for one indication for which sales would be *de minimis*, but (ii) sold in significant volume only for a separate "carved-out" indication covered by the innovator's patents. The reasonable inference is that Congress envisioned a scenario where the unpatented uses for which a generic company sought FDA approval would be significant; not a pretext for making sales that would infringe method-of-use patents covering the product's main indication.

This case, like *Novartis Pharms. Corp. v. Wockhardt USA LLC*, No. 13-1028, 2013 WL 5770539, at *10 (D.N.J. Oct. 23, 2013) (*Reclast*®), presents a situation in which the "carve-out" indication is the *only* substantial use for a drug. In this situation, the elements of a claim for contributory infringement are satisfied, and the integrity of the section viii carve out provision as envisioned by Congress is not jeopardized.

2. Takeda Has Alleged The Requisite Elements of Contributory Infringement

(a) Takeda Sufficiently Alleges that Defendants' Proposed Generic Products are Especially Made To Treat Gout Flares

Par argues that its proposed generic product is not especially made to infringe Takeda's gout patents, because it can treat FMF. (*See* Par Br. at 12-13.) This argument is specious. Colchicine is, first and foremost, a gout medication, as Watson's counsel emphasized at the Rule

[8] *Sigma-Tau Pharmaceuticals, Inc. v. Schwetz*, 288 F.3d 141, 146 (4th Cir. 2002), also cited by Par, is inapposite, as it involves a claim arising under the Orphan Drug Act ("ODA") and involves neither the Hatch-Waxman Act nor patent infringement claims.

16 conference, and further emphasizes in its own brief. (*See* Watson Br. at 5 ("Colchicine . . . has been continuously used . . . since [1820] for treatment of gout.").) Indeed, in amending its ANDA from one seeking approval to sell generic Colcrys® to treat gout to one seeking approval to treat FMF, Par made no change to its proposed product, demonstrating that its product is especially made to treat gout. A product with some other use(s) may still be "especially made" for an infringing use. *See, e.g.*, *ClearValue, Inc. v. Pearl River Polymers, Inc.*, 735 F. Supp. 2d 560, 575 (E.D. Tex. 2010) *rev'd on other grounds*, 668 F.3d 1340 (Fed. Cir. 2012).

(b) Takeda Sufficiently Alleges that Defendants' Proposed Generic Products Have No Substantial Noninfringing Use

Both Watson and Par argue that the mere fact that their generic products can be used to treat FMF indicates that those products have a "substantial noninfringing use" with regard to Takeda's gout patents. This argument is meritless.

First, of course, use of generic colchicine to treat FMF is also covered by Takeda's patents. Takeda thus contends that it is not a "*non-infringing* use" under the statute. *See Abraxis Bioscience, Inc. v. Navinta, LLC*, 640 F. Supp. 2d 553, 571 (D.N.J. 2009), *rev'd and vacated on other grounds*, 625 F.3d 1359 (Fed. Cir. 2010) ("In analyzing whether something is 'suitable for substantial non-infringing use,' the Court should consider whether the product infringes other patents in addition to the method of use patents asserted in the instant action."); *see also Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1320 (Fed. Cir. 2009).

Second, the rarity with which generic colchicine would be prescribed in the United States to treat FMF does not constitute a "substantial" use, even were that use not subject to Takeda's patents. Both Par and Watson recite an incorrect legal standard for determining whether a product accused of contributory infringement has a "substantial noninfringing use," relying on language from a Supreme Court's copyright decision stating that liability cannot lie if the accused product is

"'unsuited for any commercial noninfringing use.'" *Sony Corp. of Am. v. Universal City Studios, Inc.*, 464 U.S. 417 (1984) (quoting *Dawson Chem. Co. v. Rohm & Hass Co.*, 448 U.S. 176, 198 (1980)). The language in *Sony*, however, merely quotes *Dawson*'s reference to the *facts* in early Supreme Court cases involving the intersection of patent misuse and contributory infringement law. Elsewhere, *Sony* acknowledges that, to avoid contributory infringement, a product must be "*widely used* for legitimate, unobjectionable purposes," and be "capable of commercially *significant* noninfringing uses." *Sony*, 464 U.S. at 442 (emphasis added). These descriptions track the language of the statute, which specifies that contributory infringement may be found so long as the accused component is not "suitable for *substantial* noninfringing use."

Defendants then note that generic colchicine can be used to treat FMF, and argue that this alone eliminates any possible contributory infringement claim.[9] However, Takeda has alleged that the use of Colcrys® to treat FMF is both "unusual" and infrequent, and that FMF patients are not "the intended market" for the generic product. *See Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1362 (Fed. Cir. 2010). Defendants do not meaningfully dispute this. Neither defendant refutes the prescription data or physician testimony demonstrating that the FMF market in the United States is insignificant. To the contrary, Watson has emphasized its belief that it is critical to supply generic colchicine to the large gout market, while making no mention of the miniscule FMF market. For these reasons, Takeda has sufficiently alleged a claim for contributory infringement at the pleadings stage. *Reclast*®, 2013 WL 5770539, at *10.

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[9] Watson also argues that pre-patent use of unapproved colchicine to treat FMF and gout also qualify as "non-infringing uses." However, the FDA ordered cessation of the distribution of any non-FDA-approved uses of colchicine in 2010. *See* Declaration of Mary W. Bourke (hereinafter, "Bourke Decl."), Ex. A.)

Par's reliance on *Aventis Pharma Deutschland GmbH v. Cobalt Pharmaceuticals, Inc.*, 355 F. Supp. 2d 586 (D. Mass. 2005) is misplaced. In *Aventis*, the generic filer sought approval for two substantial uses in the public domain, and carved out a patented method of use for treating heart failure. *Id*. at 588, 590. The court dismissed the contributory infringement claims because the patented use (the basis for the contributory infringement claim) would only generate "some sales revenue," i.e., it was indisputably not the only substantial use. *Id.* at 598-99 & n.134. In contrast, here, Defendants do not meaningfully contest that the use of colchicine to prevent and treat gout flares is the only substantial use for their generic colchicine products and that the treatment of FMF is insubstantial.

C. Takeda Brings This Motion in Good Faith Without Undue Delay and There Would Be No Undue Prejudice to Par if the Court Grants Takeda's Motion

Watson does not argue that Takeda acted in a dilatory manner or in bad faith. Takeda informed Watson that it intended to assert its gout patents within four days of Watson's informing Takeda that it was changing its Paragraph IV certification to include a section viii carve-out for gout. Although Par accuses Takeda of delay and bad faith, those claims are unfounded. Par faults Takeda for wanting to await the Court's determination of the scope of the case before proceeding with fact witness depositions. This Court, however, recently agreed that deferring those depositions until the scope of the case is settled is the most efficient way to proceed for both the parties and the relevant witnesses. (Bourke Decl., Ex. B.) Par even goes so far as to suggest that Takeda intentionally included an erroneous proposed amended complaint as an exhibit to its original motion to defer determination of the present motion. In fact, the errors in the complaint—which related solely to the specific statutory provisions cited as the basis for the various causes of action—were wholly inadvertent; as soon as Takeda identified them, it corrected the complaint, and, at Defendants' request, gave them additional time to file their oppositions.

Takeda brought its motion for leave to amend well within the time for such motions under the Court's scheduling order after having engaged in discovery sufficient to confirm its (and, as subsequent fact discovery established) Defendants' understanding of the nature of the U.S. FMF and gout markets. (*See* Takeda's Mot. 8-9.) Conclusory allegations of delay are insufficient to establish undue prejudice from a proposed amendment of the pleadings. *See Adams v. Gould, Inc.*, 739 F.2d 858, 868 (3d Cir. 1984). Here, Par fails to point to any concrete prejudice that it will suffer from the amendment Takeda seeks. Indeed, at the July 23, 2013 hearing in the stayed gout cases—after Par carved out the gout indication—Par argued that its case should remain consolidated with Amneal's case, which at that time still included the gout patents. (Yang Decl., Ex. G.). Par then argued that it was in the best interest of the parties and the Court to try the gout patents and FMF patents together, because the seventeen patents, *inter alia*, "deal with one concept," are from the same "three families of patents," "have the same common inventor," present the "same noninfringement argument[s]," have "the same prior art," and require "the same type of experts." (*Id.* at 11:16-12:11.) Par should hardly now be heard to argue that adding the gout patents to the case will cause undue prejudice.[10]

III. CONCLUSION

For these reasons, Takeda respectfully requests that the Court grant its motions for leave to amend the complaints in the above-referenced matters.

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[10] Defendants also repeatedly refer to the total number of Takeda patents that would be in suit if the Court allows Takeda to add the gout patents. Takeda appreciates the Court's desire to streamline this case, and will be responsive to the Court's direction in that regard. Takeda submits, however, that the Court's entirely legitimate interest in limiting the litigation to a manageable scope can be accomplished by means other than denying Takeda the ability to assert otherwise cognizable contributory infringement claims.

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Dated: July 10, 2014

CERTIFICATE OF SERVICE

I hereby certify that on July 10, 2014, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to all registered participants.

Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on July 10, 2014, upon the following individuals via electronic mail:

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